IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Civil Action No: 2:15-cv-00384-GP

HEATHER WALSH,

Plaintiff,

vs.

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

Defendants.
_____/

FIRST AMENDED COMPLAINT

AND NOW COMES the PLAINTIFF, HEATHER WALSH, ("Walsh" or "Plaintiff"), by and through undersigned counsel, files this First Amended Complaint against Defendants, BAYER CORP., BAYER HEALTHCARE, LLC., BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G. (Collectively the "Bayer Defendants" or "Defendants") and in support thereof makes the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, Walsh is a citizen of MI.

2. BAYER CORP. is a for-profit corporation incorporated in the state of Indiana with its principal place of business in the Commonwealth of PA at 100 Bayer Road, Building 4, Pittsburgh, PA 15205. Defendant is authorized to do and does business throughout the Commonwealth of PA.

3. BAYER CORP. is the parent corporation of BAYER HEALTHCARE, LLC, BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC. (the "Bayer subsidiaries"). BAYER CORP. owns 100% of the Bayer subsidiaries.

4. BAYER CORP. is wholly owned by BAYER A.G.

5. BAYER A.G. is a German for-profit corporation. Defendant is authorized to do and does business throughout the Commonwealth of PA.

6. At all relevant times, the Bayer subsidiaries are agents or apparent agents of BAYER CORP. and/or BAYER A.G. Each Defendant acted as the agent of the other Defendant and acted within the course and scope of the agency, regarding the acts and omissions alleged. Together, the Defendants acted in concert and or abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves and creating an injustice at the expense of Plaintiff.

7. In addition, the Bayer subsidiaries, individually and/or collectively, are "Alter Egos" of BAYER CORP. and/or BAYER A.G. as, *inter alia,* they are wholly owned by BAYER CORP; share the same trademark; share management and officers; and in other ways were dominated by BAYER CORP and/or BAYER A.G.

8. Moreover, there exists and at all times mentioned herein existed a unity of interest in ownership and among all Defendants such that individuality and separateness between and among them has ceased. Because Defendants are "Alter Egos" of one another and exert control over each other, adherence to the fiction of the separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud, and promote injustice. BAYER CORP. and BAYER A.G. wholly ignored the separate status of the

Bayer subsidiaries' separate status and so dominated and controlled its affairs that its separate entities were a sham.

9. BAYER HEALTHCARE, LLC. is a for-profit corporation incorporated in the state of DE. Defendant is authorized to do and does business throughout the Commonwealth of PA.

10. BAYER ESSURE, INC. is a for-profit corporation incorporated in the state of DE. Defendant is authorized to do and does business throughout the Commonwealth of PA.

11. BAYER HEALTHCARE PHARMACEUTICALS, INC. is a for-profit corporation incorporated in the state of DE. Defendant is authorized to do and does business throughout the Commonwealth of PA.

12. Venue is proper in Philadelphia County as Defendants regularly conduct business in Philadelphia County.

INTRODUCTION

13. This Complaint is brought by Plaintiff who was implanted with a female birth control device, known as "Essure." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in reality, the device migrates from the tubes, perforates organs, breaks into pieces, and/or corrodes wreaking havoc on the female body.

14. As a result of (1) Defendants' negligence described *infra* and (2) her reliance on Defendants' warranties and representations, Defendants' Essure device migrated from Plaintiff's fallopian tubes to her uterus/rectum, requiring five hospitalizations and an eventual hysterectomy. Plaintiff now also suffers from auto-immune and adhesion disorders.

15. Essure had **Conditional**[1] Premarket Approval ("CPMA") by the Food and Drug Administration ("FDA"). As discussed below, this CPMA became "invalid" and the product "adulterated" and "misbranded", pursuant to (1) **the FDA** due to Defendants' failure to conform with the FDA requirements prescribed in the CPMA and (2) **violations of Federal Statutes and Regulations** noted *infra.*

16. Pursuant to Defendants' CPMA (which reads: "**Failure to comply with conditions of approval invalidates this approval order**"), the C.F.R, and Federal Food, Drug and Cosmetic Act ("FD&C Act"):

(a) the CPMA is invalid; and

(b) the product is "adulterated" and "misbranded" and thus, **could not have been marketed or sold to Plaintiff.**

17. Specifically, the CPMA became invalid as Defendants (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with Federal laws regarding marketing and distribution as specifically described *infra.*

18. The fact that Defendants failed to comply with these conditions is not a mere allegation made by Plaintiff. These failures to comply with both the CPMA and Federal regulations are memorialized in **several FDA findings,** including Notices of Violations and Form 483's issued by the FDA.

19. As discussed in greater detail *infra*, Defendants were **cited by the FDA** and the Department of Health for:

(a) **failing to report** and **actively concealing 8 perforations which occurred as a result of Essure;**

(b) erroneously **using non-conforming material** in the manufacturing of Essure;

[1] All Emphasis is supplied in this Complaint.

(c) failing to use **pre-sterile and post-sterile cages;**

(d) manufacturing Essure **at an unlicensed facility**; and

(e) manufacturing Essure for three years **without a license to do so.**

20. Defendants were also found, by the FDA, to be:

(a) Not reporting ... complaints in which their product migrated;

(b) **Not reporting to the FDA incidents of bowel perforation, Essure coils breaking into pieces and migrating out of the fallopian tubes.**

(c) Only disclosing 22 perforations while having knowledge of 144 perforations;

(d) Not considering these complaints in their risk analysis for the design of Essure;

(e) Failing to have a complete risk analysis for Essure;

(f) Failing to analyze or identify **existing and potential** causes of **non-confirming product** and other **quality problems;**

(g) **Failing to track the non-conforming product;**

(h) **Failing to follow procedures used to control products which did not confirm to specifications;**

(i) Failing to have complete Design Failure Analysis;

(j) Failing to document CAPA activities for a supplier corrective action;

(k) Failing to disclose **16, 047 complaints to the FDA as** MDR's (Medical Device reports which are suspected from device malfunction or associated with injury); and

(l) Failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two year report schedules.

21. Most egregiously, on May 30, 2013, the **FDA uncovered an internal excel spreadsheet with 16,047 entries** for complaints which were not properly reported to the FDA. Here, Defendant did not disclose to the FDA complaints where its product **migrated outside of the fallopian tube**. Defendants excuse was that those complaints were not reported because the

patients were "not –at last contact- experiencing pain....and were mere trivial damage that does not rise to the level of a serious injury." Accordingly, the FDA **again** warned Defendants **for violations of the FD&C Act.**

22. As a result, Defendants' CPMA is "invalid," and the "adulterated" and "misbranded" product, Essure, which was implanted in Plaintiff should never have been marketed or sold to Plaintiff **pursuant to Federal law.**

23. Lastly, Defendants concealed and **altered the medical records of its own trial participants to reflect favorable data. Specifically, Defendants altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.** Subsequently, Defendants failed to disclose this and concealed it from Plaintiff and her Implanting physician.

24. Notwithstanding the invalid CPMA, Plaintiff's causes of action are all based on deviations from the requirements in the CPMA and/or violations of Federal statutes and regulations.

25. Plaintiff's first four causes of action have nothing to do with the product itself, but rather Defendants' negligence in (1) failing to abide by FDA-Approved training guidelines when training Plaintiff's implanting physician ("the implanting physician"); (2) entrusting the implanting physician with specialized hysteroscopic equipment he was not qualified to use; and (3) distributing/over promoting its product in an unreasonably dangerous manner, as fully discussed below, **all of which violated its CPMA and/or Federal statutes or regulations.**

26. The entrustment of specialized hysteroscopic equipment to the implanting physician and method of distribution did not have any type of approval by the FDA.

27. Plaintiff's causes of action five through nine are based entirely on the express warranties, misrepresentations, and Defendants' deceptive conduct, which were relied upon by Plaintiff prior to having the device implanted. Under Pennsylvania law, Plaintiff's claims for breach of express warranties are not preempted by the Medical Device Act ("MDA"). *Rosci v Acromed, Inc.*, 447 Pa. Super. 403 (1995); *Bentzley v Medtronic, Inc.*, 2011 U.S. Dist. Lexis 136570 (E.D. Pa. Nov. 28, 2011).

28. The remaining causes of action are related to the product itself and center on violations of the CPMA requirements and Federal statutes and regulations.

29. In addition, according to the FDA's order, the CPMA order became invalid because Defendants failed to comply with the following express conditions and Federal regulations:

(a) "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(b) "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(c) Report Due Dates- six month, one year, eighteenth month, and two year reports.

(d) A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

(e) Effectiveness of Essure is established by annually reporting on the 745 women who took place in the clinical tests.

(f) Successful bilateral placement of Essure is documented for newly trained physicians.

(g) Warranties are truthful, accurate, and not misleading.

(h) Warranties are consistent with applicable Federal and State law.

30. These violations invalidated the CPMA, rendered the product "adulterated" and "misbranded"- precluding Defendants from marketing or selling Essure per the FDA, and, more importantly endangered the life of Plaintiff and hundreds of thousands of women.

31. Defendants actively concealed these violations and never advised Plaintiff of the same. Had Plaintiff known that **Defendants were concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license to do the same**, she never would have had Essure implanted.

DESCRIPTION OF ESSURE AND HOW IT WORKS

32. Essure is a permanent form of female birth control (female sterilization). The device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage.

33. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. All components are intended for a single use. *See Exhibit "A" for a description of Essure.*

34. The micro-inserts are comprised of two metal coils which are placed in a woman's fallopian tubes via Defendants' disposable delivery system and under hysteroscopic guidance (camera).

35. The hysteroscopic equipment needed to place Essure was manufactured by a third party, is not a part of Defendants' CPMA, and is not a part of Essure. However, because

Plaintiff's implanting physician did not have such equipment, Defendants provided it so that it could sell Essure. *See Exhibit "A" for a description of hysteroscopic equipment.*

36. The coils are comprised of nickel, steel, nitinol, and PET fibers. In other words, the coils are metal-on-metal.

37. Defendants' disposable delivery system consists of a single handle which contains a delivery wire, release catheter, and delivery catheter. The micro-inserts are attached to the delivery wire. The delivery handle controls the device, delivery, and release. Physicians are allowed to visualize this complicated process through the hysteroscopic equipment provided by Defendants.

38. After placement of the coils in the fallopian tubes by Defendants' disposable delivery system, the micro-inserts expand upon release and are intended to anchor into the fallopian tubes. The PET fibers in the coil allegedly elicit tissue growth blocking off the fallopian tubes.

39. The coils are alleged to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

40. After three months following the device being implanted, patients are to receive a "Confirmation" test to determine that the micro-inserts are in the correct location and that the tissue has created a complete occlusion. This is known as a hysterosalpinogram ("HSG Test" or "Confirmation Test").

41. Regardless of the Confirmation Test, Defendants warrant that Essure allows for visual confirmation of each insert's proper placement **during the procedure**.

42. Essure was designed, manufactured, and marketed to be used by the average gynecologists throughout the world, as a **"quick and easy"** and **"non-surgical"** outpatient procedure to be done without anesthesia.

EVOLUTION OF ESSURE

43. Essure was first designed and manufactured by Conceptus, Inc. ("Conceptus").

44. Conceptus and Defendants merged on or about April 28, 2013.

45. For purposes of this lawsuit, Conceptus and Defendants are one in the same.

46. Essure, a Class III medical device, is now manufactured, sold, distributed, marketed, and promoted by Defendants.

47. Defendants also trained physicians on how to use its device and other hysteroscopic equipment, including Plaintiff's implanting physician.

48. Prior to the merger between Conceptus and Bayer defendants, Conceptus obtained CPMA for Essure.

49. By way of background, Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

50. PMA is intended to be a stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA.

51. An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device- assuming it complies with federal laws, any CPMA order and is not "adulterated" or "misbranded."

52. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is normally longer. Before approving or denying a PMA, the appropriate

FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission.

53. However, the PMA process for Essure was "expedited" and several **trial candidates' medical records were altered to reflect favorable data.**

54. According to the FDA, a class III device that **fails to meet CPMA requirements** is considered to be **adulterated under section 501(f)** of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") **and cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.**

55. Regarding the Premarket Approval Process, devices can either be "approved," "conditionally approved," or "not approved."

56. Essure was **"conditionally approved"** or in other words, had only CPMA not outright PMA, the "gold standard."

57. In the CPMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval **invalidates this approval order**[2]." The following were conditions of approval:

(a) "Effectiveness of Essure is established by annually reporting on the 745 women who took part in clinical tests."

(b) "Successful bilateral placement of Essure is documented for newly trained physicians."

(c) "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA."

(d) "Report to the FDA whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

(e) Effectiveness of Essure is established by annually reporting on the 745 women who took place in the clinical tests.

[2] Note: The CPMA order does not read...failure to comply *may* invalidate the order.

(f) Successful bilateral placement of Essure is documented for newly trained physicians.

(g) Warranties are truthful, accurate, and not misleading.

(h) Warranties are consistent with applicable Federal and State law.

58. Although failure to comply with just *one* of the conditions invalidated the CPMA Order, Defendants failed to comply with *several* conditions; thereby invalidating the CPMA pursuant to the very language of the CPMA order. Specifically:

(a) Defendants failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. Defendants also failed to timely submit post approval reports for its six month, one year, eighteen month **and** two year reports. All reports failed to meet the respective deadlines. *Post approval Studies- ESS-305 Schedule attached as Exhibit "B."*

(b) Defendants failed to document successful placement of Essure concealing the failure rates.

(c) Defendants failed to notice the FDA of several adverse reactions and actively concealed the same. Defendant **failed to report 8 perforations** which occurred as a result of Essure **and was cited for the same by the FDA** via Form 483.[3] *See Investigative Report attached as Exhibit "C."*

(d) Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendants **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483. *See Investigative Report attached as Exhibit "C."*

(e) As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

(f) Defendants' warranties were not consistent with applicable Federal and State law.

(g) Defendants failed to notice the FDA of their internal excel file containing **16,047 entries of complaints.**

59. Defendants also were found to be:

[3] Form 483 is issued to firm management at the conclusion of inspection when an FDA investigator has observed any conditions that violate the FD&C Act rendering the device "adulterated."

(a) erroneously **using non-conforming material** in the manufacturing of Essure and not tracking where it went; *See Investigative Report attached as Exhibit "C."*

(b) failing to use **pre-sterile and post-sterile cages;** *See Exhibit "D."*

(c) manufacturing Essure **at an unlicensed facility**; *See Exhibit "D."*

(d) manufacturing Essure for three years **without a license to do so**. *See Exhibit "D."*

(e) Not reporting ... complaints in which their product migrated; See *Exhibit "E."*

(f) Not considering these complaints in their risk analysis for the design of Essure; See *Exhibit "E."*

(g) Failing to document CAPA activities for a supplier corrective action; See *Exhibit "E."*

60. Specifically,

(a) On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011. **These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes.** Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

(b) Defendants had notice of 168 perforations but only disclosed 22 to the FDA. *Id.*

(c) On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure **didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity**. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(d) On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, **the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures.** The FDA found that Defendants' engineers

learned of this and it was not documented. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

(e) On July 7, 2003, Defendants were cited for not analyzing to identify **existing and potential causes of non-conforming** product and **other quality problems.** Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, **which is used to track the data.** (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went) See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

(f) On July 7, 2003, Defendants were cited for **not following procedures used to control products which did not confirm to specifications.** See Exhibit "G." Form 483/Violation form issued by Mark E. Chan on July 7, 2003.

61. In response Defendants admitted that "the device may have caused or contributed to a death or serious injury, and an MDR Report is required to be submitted to FDA."

62. Next, per the FDA, "a PMA may be sold to another company" however "The sponsor **must submit a PMA amendment** to notify the FDA of the new owner...The...supplement should include: the effective date of the ownership transfer; a statement of the new owner's commitment to comply with all the conditions of approval applicable to the PMA; and either a statement that the new owner has a complete copy of the PMA including all amendments, supplements, and reports or a request for a copy from the FDA files."

63. There were 36 PMA supplements filed with the FDA in regard to Essure (P020014). **None of the PMA supplements included notification of the new owner** (Defendants).

64. Lastly, although Essure appears at first glance to be a "medical device," Defendants actually categorize it as a "drug." See Exhibit "H."

65. In short, (1) the CPMA is invalid **per the FDA's CPMA order;** (2) Essure is considered an "adulterated" and "misbranded" product that could not have been marketed or sold to Plaintiff **per the FDA and Federal law;** (3) the invalid CPMA was not properly transferred to

Bayer and, therefore, Defendants do not even have CPMA for Essure; and (4) all of Plaintiff's claims center around violations of the CPMA requirements and/or Federal regulations and statutes.

DEFENDANTS' TRAINING, ENTRUSTMENT, AND DISTRIBUTION PLAN

66. Defendants (1) failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physician; (2) provided specialized hysteroscopic equipment to the implanting physician who was not qualified or competent to use the same; and (3) created an unreasonably dangerous distribution plan, all of which were aimed at capitalizing on and monopolizing the birth control market at the expense of Plaintiff's safety and well-being.

67. Because Essure was the first device of its kind, the implanting physician was **trained by Defendants** on how to properly insert the micro-inserts using the disposable delivery system and was given hysteroscopic equipment by Defendants.

68. In order to capture the market, Defendants independently undertook a duty of training physicians outside of FDA guidelines, including the implanting physician, on how to properly use (1) its own mechanism of delivery and (2) the specialized hysteroscopic equipment manufactured by a third party.

69. Regarding Essure, Defendants' Senior Director of Global Professional Education, stated, "**training is the key factor** when clinicians choose a new procedure" and "For the Essure procedure, the patient is **not under anesthesia**, therefore **a skilled approach is crucial**."

70. In fact, because gynecologists and Plaintiff's implanting physician were unfamiliar with the device and how to deliver it, Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created Essure

Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures."

71. Defendants provided no training to the implanting physician on how *to remove* Essure should it migrate.

72. Defendants also kept training records on all physicians "signed-off to perform Essure procedures."

73. In order to sell its product and because the implanting physician did not have access to the expensive hysteroscopic equipment, Defendants **provided the implanting physician with hysteroscopic equipment** which, although is not a part of Essure, is needed to implant Essure. The entrustment of this equipment is not part of any CPMA.

74. In fact, Defendants entered into agreements with Johnson & Johnson Co., Olympus America, Inc., Richard Wolf Medical Instruments Corp., and Karl Storz Endoscopy, America, Inc. (1) to obtain specialized hysteroscopic equipment to then give to physicians and (2) to increase its sales force to promote Essure.

75. According to Defendants, these agreements allowed Defendants to "gain market presence…and expand … market opportunity by driving adoption among a group of physicians."

76. In regard to the entrustment of such specialized equipment, Defendants admitted: **"We cannot be certain how successful these programs will be, if at all."** *See US SEC Form 10-Q: Quarterly Report Pursuant to Section 13 or 15(d)of the SEC Act of 1934.*

77. Defendants "handed out" this hysteroscopic equipment to unqualified physicians, including Plaintiff's implanting physician, in an effort to sell its product.

78. Defendants knew or failed to recognize that the implanting physician was not qualified to use such specialized equipment yet provided the equipment to the unqualified implanting physician in order to capture the market.

79. In return for providing the expensive hysteroscopic equipment, **Defendants required that the implanting physician purchase two Essure "kits" per month**. This was a part of Defendants' unreasonably dangerous and negligent distribution plan aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff.

80. Defendants' distribution plan included requiring the implanting physician to purchase two (2) Essure "kits" per month**, regardless of whether he used them or not.** This distribution plan created an environment which induced the implanting physician to "push" Essure and implant the same into Plaintiff.

81. In short, Defendants used the expensive hysteroscopic equipment to induce the implanting physicians into an agreement as "bait." Once the implanting physician "took the bait" he was required to purchase two (2) Essure "kits" per month, regardless of whether he sold any Essure "kits".

82. This was an unreasonably dangerous distribution scheme as it compelled the implanting physician to sell two (2) devices per month at the expense of Plaintiff's safety and well-being.

83. Defendant's distribution plan also included (1) negligently distributing Essure in violation of FDA orders and Federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (4) failing to report and actively concealing adverse events which occurred as

a result of Essure; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure at an unlicensed facility and (8) manufacturing Essure for three years without a license to do so.

84. In short, Defendants (1) failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physician; (2) provided specialized hysteroscopic equipment to implanting physicians who were not qualified to use the same; and (3) created an unreasonably dangerous distribution and reporting plan aimed at capitalizing and monopolizing the birth control market.

85. All of this was done in violation of Federal law and its CPMA. Unfortunately, this was done at the expense of Plaintiff's safety.

PLAINTIFF'S HISTORY

86. In October 2008, Plaintiff went to the implanting physician to have Essure implanted in her fallopian tubes. The implanting physician advised Plaintiff that a representative from Defendants would be present to supervise the procedure.

87. During this visit, Defendants' representative failed to attend and supervise the procedure. The implanting physician attempted to insert the device on his own with the delivery system and hysteroscopic equipment.

88. After several attempts, the implanting physician was unable to place the device and re-scheduled Plaintiff's implantation for another date to make sure Defendants' representative would be present.

89. Plaintiff returned to the implanting physician the following month. Defendants failed to attend and supervise the procedure again, and the implanting physician attempted to place the device.

90. Without Defendants' representative present, the implanting physician attempted to place the device several times. Finally, the micro-inserts were placed into Plaintiff.

91. After two years, Plaintiff was then hospitalized four times due to severe pain, fever, and fainting spells.

92. Eventually a CT scan revealed that one of the micro-inserts had migrated from the fallopian tube and became lodged in or behind her colon.

93. It was also discovered that there were **three micro-inserts** inside of Plaintiff, instead of two.

94. On March 4, 2013, as a result of Essure, Plaintiff underwent a complete hysterectomy and an additional surgery to remove the coil lodged in her colon. Plaintiff now suffers from several autoimmune and adhesion disorders.

95. Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until her hysterectomy on or about March 4, 2013. Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

96. In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations. Most egregiously, Defendants was not only actively and fraudulently concealing adverse reports of migrations and perforations from Plaintiff but also from the FDA. This active concealment is not a mere allegation, but evidenced by FDA findings and its citation to Defendants for failing to report perforations and migrations.

97. Defendants' conduct was malicious, intentional, and outrageous, and constitutes a willful and wanton disregard for the rights and safety of Plaintiff and others.

FACTS AND WARRANTIES

98. First, Defendants failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physician, including the implanting physician, on how to use its device and in hysteroscopy.

99. The skills needed to place the micro-inserts as recognized by the FDA panel in the PMA process "are way beyond the usual gynecologist."

100. Accordingly, Defendants went out and attempted to train the implanting physician on (1) how to use its device and (2) in hysteroscopy. Defendants (1) created a "Physician Training Manual"; (2) created a simulator called EssureSim; (3) organized limited training courses-where Defendants observed physicians until Defendants believed they were competent; (4) created Essure Procedure Equipment Supplies Checklists; and (5) represented to Plaintiff that "Physicians must be signed-off to perform Essure procedures." Defendants had no experience in training others in hysteroscopy.

101. Defendants failed to abide by FDA-Approved training guidelines when training Plaintiff's implanting physician and provided hysteroscopic equipment to the implanting physician who was not qualified to use such complicated equipment.

102. A key study found that a learning curve for this hysteroscopic procedure was seen for procedure time, **but not for successful placement**, pain, and complication rates, evidencing that Defendants' training methods were failing[4].

[4] *Learning curve of hysteroscopic placement of tubal sterilization micro inserts*, US National Library of Medicine, Janse, JA.

103. Second, Defendants provided hysteroscopic equipment to the implanting physician who was not competent to use such device. Defendants knew the implanting physician was not competent to use such sophisticated equipment, yet provided the equipment anyway in order to sell its product.

104. Third, Defendants' distribution plan of requiring the implanting physician to purchase two (2) Essure kits a month, was an unreasonably dangerous plan as it compelled the implanting physician to insist that Essure be used in Plaintiff.

105. Defendants' distribution plan also included (1) negligently distributing an "adulterated" and "misbranded" device against its CPMA and Federal law; (2) the promotion of Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (3) failing to report and actively concealing perforations which occurred as a result of Essure; (4) erroneously using non-conforming material in the manufacturing of Essure and failing to keep track of the non-conforming material; (5) failing to use pre-sterile and post-sterile cages; (6) manufacturing Essure at an unlicensed facility and (7) manufacturing Essure for three years without a license to do so.

106. Lastly, Plaintiff relied on the following warranties by Defendants, prior to implantation, on the internet and in the implanting physician's office, through Defendant's website and advertising, as outlined in detail below:

WEBSITE WARRANTIES

107. Defendants marketed on its website the following:

(a) "Only FDA approved female sterilization procedure to have **zero** pregnancies in the clinical trials."

i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(b) "There were Zero pregnancies in the clinical trials."

i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(c) "Physicians must be signed-off to perform Essure procedures"

i. However, Defendants failed to abide by the FDA guidelines when training the implanting physician and "signed-off" on the implanting physician who did not have the requisite training. Defendants concealed this information from Plaintiff.

(d) "Surgery-free"

i. However, Essure is not "surgery-free", rather surgery is not required. Moreover, **all Essure procedures are done under hysteroscopy, which is a surgical procedure.**

(e) "Worry free: Once your doctor confirms that your tubes are blocked, you **never** have to worry about unplanned pregnancy"

i. However, several pregnancies have been reported subsequent to confirmation. Defendants concealed this information from Plaintiff.

ii. However, between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff.

i. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. Defendants concealed this information from Plaintiff.

ii. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

iii. However, women who have Essure have **10 times greater risk** of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater[5].

[5] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014.

iv. Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by Defendants** as "**painful and is also known to be highly inaccurate, with false-positive results in as many as 40%.**"

(f) "Essure is the most effective permanent birth control available-even **more effective than tying your tubes or a vasectomy**."

i. Yet, Defendants' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by Defendants. Defendants stated, "**We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation.**" Defendants concealed this information from Plaintiff.

ii. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[6].

(g) "Correct placement…is **performed easily** because of the design of the micro-insert"

i. However, Defendants admitted that placement of the device requires a "skilled approach" and even admitted that their **own experts in hysteroscopy** (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. Defendants concealed this information from Plaintiff.

(h) "an **Essure trained** doctor inserts spring-like coils, called micro-inserts…"

i. However, the implanting physician who implanted the device was not trained by Defendants pursuant to FDA guidelines. Defendants concealed this information from Plaintiff.

(i) "the Essure training program is a comprehensive course designed to provide information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control."

i. However, Defendants failed to train the implanting physician pursuant to the FDA guidelines. Defendants concealed this information from Plaintiff.

(j) "In order to be trained in Essure you **must be a skilled operative hysteroscopist.** You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If

[6] *Id.*

your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."

i. However, Defendants "signed off" on the implanting physician who was not a skilled operative hysteroscopist, in order to monopolize and capture the market, including the implanting physician. Defendants concealed this information from Plaintiff.

(k) "Essure is a surgery-free **permanent birth control.**"

i. However, Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

ADVERTISEMENT WARRANTIES

108. Defendants advertised:

(a) "Zero pregnancies" in its clinical or pivotal trials.

i. However, there were at least four pregnancies. Defendants concealed this information from Plaintiff.

(b) In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

i. However, Defendants "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physician. Defendants concealed this information from Plaintiff.

(c) No pregnancies have occurred after a successful confirmation test in the Essure clinical studies at 4 and 5 years of follow up.

i. However, there were at least four pregnancies. Defendants concealed this information from Plaintiff.

(d) I don't want to worry about an unexpected pregnancy

i. However, there were at least four pregnancies. Defendants concealed this information from Plaintiff.

FACT SHEET WARRANTIES

109. Defendants represented in its Fact Sheet:

(a) Data from two clinical studies show that 99 percent of women who had the Essure procedure rated their long-term comfort with the micro-inserts as 'good,' 'very good' or 'excellent'."

i. However, the actual choices given to the clinical participants were 'poor,' 'very good' or 'excellent.' Defendants concealed this information from Plaintiff.

ii. Moreover, Defendants altered medical records of trial participants to reflect favorable data.

WARRANTIES BY AGENTS

110. Defendants' Senior Director of Global Professional Education represented to the public that "For the Essure procedure, the patient is not under anesthesia, therefore a **skilled approach** is crucial."

(a) Yet, Defendants also claims that "Correct placement...is **performed easily** because of the design of the micro-insert"

111. Defendants' CEO stated: "Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme.

(a) However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. Defendants concealed this information from Plaintiff.

(b) However, between 1997-2005, 64 pregnancies were reported to Defendants. Defendants concealed this information from Plaintiff.

(c) However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

(d) Yet, Defendants' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by Defendants** as "painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

MARKETING WARRANTIES

112. Defendants marketed with commercials stating:

(a) Essure has been in use for over 5 years.

i. However, Essure was only in use for 4 years at this time. Defendants concealed this information from Plaintiff.

(b) "The non-surgical permanent birth control for woman."

i. However, the procedure is most commonly done with surgery. Defendants concealed this information from Plaintiff.

ii. However, Essure is not permanent as the coils migrate, perforate organs and are expelled by the body.

iii. However, all Essure procedures are done under hysteroscopy, which is a surgical procedure, and billed as a surgery.

113. Defendants created a fake blog entitled "Diary of a Decision" in order to induce Plaintiff to use Essure. Defendants created a fictitious person, named "Judy" who pretended to have had the procedure and answered questions from Plaintiff.

(a) However, "Judy" never had the procedure as represented and was actually Debbie Donovan. Defendants concealed this information from Plaintiff.

114. Defendants warranted that Essure "allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure Confirmation Test."

(a) However, Essure does not allow for visual confirmation of proper placement during the procedure.

BROCHURE WARRANTIES

115. Defendants' Essure brochure warrants:

(a) "Worry free"